

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SYMED LABS LIMITED, et al., .
 .
Plaintiffs, . Case No. 15-cv-08304
vs. .
 . Newark, New Jersey
ROXANE LABORATORIES, INC., . January 20, 2017
 .
Defendant. .
 .

SYMED LABS LIMITED, et al., .
 .
Plaintiffs, . Case No. 15-cv-08307
vs. .
 .
AMNEAL PHARMACEUTICALS LLC, .
 .
Defendant. .
 .

SYMED LABS LIMITED, et al., .
 .
Plaintiffs, . Case No. 15-cv-08306
vs. .
 .
GLENMARK PHARMACEUTICALS .
INC., USA, .
 .
Defendant. .

TRANSCRIPT OF HEARING
BEFORE THE HONORABLE MARK FALK
UNITED STATES MAGISTRATE JUDGE

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1 (Commencement of proceedings at 10:25 A.M.)

2

3 THE COURT: All right. Good morning, counsel.

4 This is Symed Labs, et al., versus Roxane, 15-8304; Symed

5 Labs versus Glenmark, 15-8306; and Symed Labs versus Amneal,

6 15-8307.

7 Can I have the appearances of counsel, please.

8 MS. SAVERIANO: Good morning, Your Honor, Christy

9 Saveriano from Hill Wallack on behalf of the plaintiffs.

10 I have my cocounsel with me, who will introduce
11 himself.

12 MR. GRAHAM: Mark Graham for the plaintiffs,

13 Your Honor.

14 THE COURT: Okay.

15 MR. RICHTER: Good morning, Your Honor, James

16 Richter of Winston & Strawn on behalf of Glenmark

17 Pharmaceuticals. And with me today is Samantha Lerner, also

18 from Winston & Strawn.

19 THE COURT: Good morning.

20 MS. ROSE: Good morning, Your Honor, Beth Rose from

21 Sills Cummis for Roxane. With me are my cocounsel Emily

22 Melvin from Latham & Watkins.

23 MS. MELVIN: Good morning, Your Honor.

24 THE COURT: Good morning.

25 MS. VYAKARNAM: Good morning, Your Honor, Anandita

1 Vyakarnam from Budd Lerner for Amneal Pharmaceuticals.

2 THE COURT: All right. Welcome. Thank you for
3 coming in.

4 You may remember that when I got involved in case
5 management of this, given that we have patent matters, I
6 often schedule regular meetings, which I find makes it more
7 likely that cases move and issues get decided and -- you
8 know, it makes people focus on the cases; not that you
9 haven't been doing that.

10 So that is really what we're here for today. And I
11 know there was an outstanding -- somewhat of an outstanding
12 dispute over the entry of a discovery confidentiality order,
13 and -- which I'm prepared to decide today if it hasn't been
14 resolved.

15 So has that issue been resolved?

16 MS. LERNER: Your Honor, Samantha Lerner for
17 Glenmark. It has not been resolved.

18 THE COURT: It has not. Okay. Well, I'm going to
19 give you -- you may have to just be patient, but I will --
20 I'll decide that issue.

21 And let's move on beyond that. Are there other
22 issues to be discussed today? Maybe you can give me an idea
23 of what's going on, how you're making out with the scheduling
24 order, and I know there's some Markman stuff going on.

25 MS. MELVIN: Yes, Your Honor, with respect to

1 Markman, we just have one, I think, point of clarification
2 that we were hoping for with respect to the local rules, if
3 Your Honor could give us some guidance. It is with respect
4 to Local Patent Rule 4.5. And defendants' view and
5 understanding of the local rules is that if either party
6 wishes to rely on expert testimony, our understanding is they
7 would be required to present an expert declaration in
8 connection with the opening briefs, followed by the 30-day
9 expert discovery period.

10 Our understanding -- and plaintiffs can correct me
11 if this is mistaken, but we understand that their view is
12 that they would not be required to put in an expert
13 declaration with their opening brief and could merely put it
14 in with response.

15 And our concern with that is that that would, of
16 course, not leave any opportunity to depose the expert, who
17 is only disclosed for the first time in connection with the
18 responsive brief. And it would actually put the party who
19 put the expert declaration in with their open briefing in at
20 a disadvantage.

21 So we were just hoping Your Honor could provide us
22 with some clarification or if it is correct that a
23 declaration can go in with the responsive brief, we think
24 that there needs to be some mechanism to, you know, get
25 discovery from that expert and potentially respond.

1 THE COURT: It's a legitimate question, which we'll
2 try to address a little later.

3 Anything else that's going on with the case?

4 MR. GRAHAM: Your Honor, Mark Graham for the
5 plaintiffs.

6 THE COURT: Yes, sir.

7 MR. GRAHAM: Actually the context in which this
8 question arose was our joint efforts to put together the
9 joint claim construction statement, which we recently filed.
10 And we wanted to make sure that under the rules, we would
11 have an opportunity to put forward a rebuttal expert witness
12 or expert statement, if the plaintiff put in -- or the
13 defendants put in an expert statement with their initial
14 opening brief and we did not. And -- because in our
15 preliminary thought is that we may not need an expert
16 declaration with our claim construction arguments.

17 And related to that was what we felt like was an
18 absence of information, sufficient information in the joint
19 statement information about the opinion of any expert, giving
20 any specifics with regard to what that opinion may be. And
21 so in the absence of knowing in the joint statement what that
22 opinion might be, that really brought into focus for us, our
23 need to protect our client's position with regard to
24 rebuttal, since we didn't really know what kind of expert
25 opinion might be offered from the language in the joint

1 statement.

2 So we're not at all trying to cast any aspersions
3 on either party. We were trying to -- we encountered, you
4 know, a potential lack of clarity, perhaps, in at least the
5 way we were looking at the rules. So we wanted to try to ask
6 the Court for some guidance with regard to how to best
7 introduce the element of expert testimony in regard to claim
8 construction.

9 THE COURT: And we'll address that, if not
10 immediately, certainly within a day or so.

11 You know, it -- and I know you know from your
12 experience that the conduct of Markman proceedings is
13 something that to a great extent, apart from the local rules,
14 is, to some extent, left to the discretion of the district
15 judge. And there are district judges who handle the Markman
16 issue in different ways; some with full-fledged, you know,
17 hearings, and others with people doing it on papers. There's
18 a whole issue of extrinsic evidence. Experts are referred to
19 in the rules. So I understand the question, and we will --
20 we'll take it up.

21 Anything else happening? Any other problems other
22 than -- I'm going to decide that DCO issue for you. I
23 would -- frankly, it's a -- I have the outline of an opinion
24 here, which I put it in an opinion, but I'm going to -- since
25 you're here and you don't seem to have much else going on,

1 I'll ask your patience in just listening while I place it on
2 the record. Normally, I would -- but I wasn't really sure if
3 it was still extant or not. So I think I'll get to that,
4 then.

5 So this is a prescheduled conference that was set
6 up, and I think there's one more, for February 16th. If
7 things are going absolutely smoothly and there's no need for
8 that hearing, then I'd appreciate, if you wish, we can avoid
9 it or handle it by telephone, if you let me know two days in
10 advance. On the other hand, I'm happy to handle -- you know,
11 have it and meet and talk about anything there is to talk
12 about.

13 But there was an outstanding dispute over the entry
14 of a discovery confidentiality order. By way of overview,
15 this is a patent case. Plaintiffs are the -- are owners by
16 assignment of four patents covering Zyvox. I think it's
17 known as an antibiotic. The cases are consolidated for
18 discovery purposes.

19 Fact discovery presently closes on July 31st, 2017.
20 We're working on our sixth amended scheduling order. I
21 believe the parties were to have submitted or may have
22 submitted their joint claim construction and prehearing
23 statement. We've discussed a little of that today. Opening
24 Markman briefs are due at the end of February.

25 Now, some background on the DCO dispute. On

1 August 5th, the parties indicated there may be an issue with
2 agreement on the terms of a discovery confidentiality order.
3 And counsel were told -- and I don't think we were on the
4 record with this -- but I don't know -- were told to submit
5 letters if the issue could not be worked out. We did not
6 hear from the parties for a little over two months.

7 Over next conference was on October 26th, '16. The
8 night before, October 25th at 8 o'clock P.M., defendants
9 submitted a 7-page, single-spaced letter stating their
10 position with respect to the disputed terms of a DCO. And
11 basically defendants wanted the order to include certain
12 provisions restricting access to confidential and highly
13 confidential information, one, to preclude any nonattorneys
14 from seeing any protected information, confidential and
15 highly confidential information. Defendants -- that's
16 exchanged in the case. Defendants want in-counsel's [sic]
17 limited to confidential information, meaning they couldn't
18 review highly confidential information.

19 And if access to highly confidential information by
20 in-house counsel was permitted, defendants wanted in-house
21 defense counsel to be permanently barred from competitive
22 decision-making related to the technology and products
23 underlying the patents. Which is -- this was taken from your
24 submissions to me and our meetings.

25 At the conference, I directed plaintiffs to respond

1 to the October 25th submission by November 9th. No response
2 was submitted until November 22nd, when the plaintiffs asked
3 until November 29th to respond.

4 And plaintiffs put in a responsive letter on
5 November 30th.

6 On December 16th, I discussed the issue with
7 counsel in detail, and two of the provisions were resolved.
8 There was no longer a dispute over the access to basic
9 confidential information. And there's a two-year patent
10 prosecution bar was agreed to. And this is set forth in the
11 transcript of that hearing, December 16th, 2016, at page 20,
12 lines 6 through -- to 19, and page 20:22 to 21 in that
13 transcript.

14 But the issue of access to highly confidential
15 information couldn't be resolved because the -- actually
16 the -- one of the issues was that the plaintiff's letter, in
17 the Court's view, didn't provide information relating to the
18 job responsibilities and the competitive decision-making
19 activities of the two individuals that were sought to have
20 restricted access or to have access. One was John Thallemer,
21 Esquire, plaintiff's in-house patent counsel. And Mr. Suresh
22 Reddy, who is Symed's patent agent, I believe, based in
23 India.

24 I directed plaintiffs to submit a supplemental
25 letter, including declarations from the two individuals. I

1 also encouraged the parties to try to reach a compromise on
2 this, because counsel at that time had represented, rather
3 strongly, I thought, that these individuals had no
4 involvement in competitive decision-making. And there was
5 no -- there was no objection to a two-year patent prosecution
6 bar.

7 So I set a schedule, December 16th, for submission
8 of supplemental papers. I got some supplement papers
9 December 30th; declarations from Reddy and Thallemer.

10 On January 13th, defendants -- which I believe is a
11 week ago -- defendants requested an extension of time to file
12 a response to the letter saying that there was an attempt to
13 resolve the dispute. And I granted the request.

14 On January 17th, defendants submitted a response,
15 and the letter stated that the issue was not resolved, which
16 was just mentioned here again.

17 There was a compromise position referred in which
18 Messrs. Reddy and Thallemer would be able to view any
19 pleadings, briefs, court documents that reprint and/or
20 contain highly confidential information, but could not view
21 the highly confidential information in original form. So if
22 it was in a brief, they could see it, but they couldn't have
23 access to the underlying exhibit. Two unpublished,
24 nonbinding cases were cited to support this view.

25 And then defendants' letter also stated that

1 plaintiffs would not be able to provide a response to the
2 compromise position until today. So -- and then defendants
3 requested the Court simply enter the order, because, quote,
4 "This dispute has been pending for quite some time, and we
5 believe the Court has all the information it needs to make a
6 ruling." End quote.

7 So the dispute is whether Messrs. Thallemer and
8 Reddy can have access to highly confidential information.
9 Plaintiff says they should have full access. Defendants'
10 position is that the new compromise position that they can
11 view the briefs -- or the -- that reprint or contain the
12 highly confidential information but can't possess the equal
13 highly confidential information that is attached as an
14 exhibit or something.

15 The Court agrees with plaintiffs Messrs. Thallemer
16 and Reddy have shown that they are not competitive
17 decision-makers and should be permitted access to highly
18 confidential information. The issue is governed by the
19 following law of the Federal Circuit, United States Steel v.
20 United States, 730 F.2d 1465, and In re Deutsche Bank, 605
21 F.3d 1373, which cases, I'm sure, are well known to all the
22 experienced counsel sitting here today.

23 To sort of just elaborate on that law a little bit,
24 in Deutsche Bank, the Court held a party seeking a protective
25 order carries the burden of showing good cause for its

1 issuance. Same true for someone seeking to include excess
2 provisions in a DCO. That's at page 1378 of the Deutsche
3 Bank case.

4 Same case, 1378, and also U.S. Steel at page 1467,
5 counsel cannot be denied access to confidential information
6 solely on the grounds that they hold the position of in-house
7 counsel.

8 The question of question of access turns on whether
9 there's an opportunity for inadvertent disclosure, which must
10 be determined by the facts on a case-by-case --
11 counsel-by-counsel basis. Citations to both Deutsche Bank,
12 1378, and 1467, U.S. Steel.

13 The counsel-by-counsel determination turns on the
14 extent to which counsel is involved in competitive
15 decision-making with the client. Citations to the same
16 places in those cases. Competitive decision-making is,
17 quote, "shorthand for a counsel's activities, associations,
18 relationship with the client, such as to involve client's --
19 counsel's advice and participation in any or all of the
20 client's decisions, pricing, product design, et cetera, made
21 in light of similar or corresponding information about a
22 competitor."

23 So the issue really comes down to a case-by-case
24 and attorney-by-attorney analysis or inquiry into whether the
25 in-house counsel or other personnel, engages in competitive

1 decision-making that could pose a risk of inadvertent
2 disclosure.

3 The Court's conclusion, as stated, is that
4 Messrs. Thallemer and Reddy are not competitive
5 decision-makers, and there's no material risk of inadvertent
6 disclosure. Both individuals have submitted detailed
7 declarations describing their job duties and roles, and
8 nothing there seems to indicate or even be close to
9 competitive decision-making.

10 With respect to Mr. Thallemer, he states under
11 oath, he's employed by plaintiff Hetero, not Symed. Hetero
12 and Symed, while both plaintiffs, are not commonly owned or
13 controlled and are not legal affiliates. They have a
14 confidential business relationship.

15 In August 15th, he was seconded -- this is from the
16 submission by Hetero to Symed to confidentially assist Symed
17 in a very limited and informal capacity restricted to the
18 present patent disputes. His job responsibilities for
19 Hetero, he helps negotiate and draft license and other
20 agreements involving IP parties; he helps with due diligence
21 matters; clearance, opinions; and conducts various
22 patent-related searches. He assists with IP aspects of
23 transactional matters and supports IP-related litigation
24 activities, working with outside counsel, the negotiation of
25 settlement of disputes. And he states he has no involvement

1 in patent filings, save for a ministerial act of filing and
2 applications on one or two occasions to the U.S. PTO. And
3 with respect to his limited work for Symed, he has no
4 standard in-house patent counsel functions except managing
5 the litigation.

6 Mr. Reddy's declaration says his primary
7 responsibilities are to support outside counsel in
8 India-based patent litigations; conducting prior art
9 searches; preparing patent evaluations; preparing freedom to
10 operate reports; similar reports; and providing responses to
11 IP-related queries posed by customers and outside counsel.
12 And in addition, he states that any patent -- future patent
13 applications related to the substance involved in this case
14 have been filed and are issued or abandoned with limited
15 exceptions. And he says that Symed has installed a
16 companywide wall blocking Mr. Reddy from any further
17 involvement with such matters.

18 So, as I said, the Federal Circuit's case law
19 arises when an individual is involved in activities such as
20 pricing and marketing, is making design-related decisions, is
21 the sole in-house counsel for the company, operates both as
22 in-house and outside counsel in matters -- this is all from
23 U.S. Steel at 1467. And neither Mr. Thallemer nor Mr. Reddy
24 have these types of job responsibilities.

25 In addition, plaintiffs have showed convincingly

1 that they are important individuals for purposes of
2 litigating a case and having the client informed about
3 litigation positions. They seem like necessary actors who
4 should have access to the information necessary to make
5 informed decisions.

6 Now, this compromise position of allowing access
7 has been, I mean, proposed. Defendants argue that this
8 distinction is necessary because they still have concerns
9 about highly confidential information being reviewed or
10 provided to individuals within Symed and Hetero and having
11 those documents reside on email servers or other computer
12 systems where they may end up in the hands of other Symed or
13 Hetero employees.

14 They're also concerned that Reddy reports to a
15 Dr. Rayo [phonetic], who's an inventor of the Patent-in-Suit
16 and is allegedly a competitive decision-maker. The Court
17 doesn't believe that defendants' concerns warrant the
18 provision they propose.

19 I've said it before and feel strongly that
20 Thallemer and Reddy are not competitive decision-makers as
21 that is defined in the case law. And competitive
22 decision-making is really the necessary precursor to the
23 concept of inadvertent disclosure.

24 The Court finds it's not present here.

25 I think there have been some novel theories of

1 | inadvertent disclosure here based on someone essentially
2 | stealing something from an email server or secretly passing
3 | information to someone else in the company. And it seems to
4 | the Court that one could always create a scenario in which
5 | highly confidential information could be passed on. But you
6 | could do that with what's already even been agreed to in this
7 | case, that defendants could view something in a brief and
8 | theoretically pass that on.

9 | The concern that Mr. Reddy may somehow run the
10 | information back to his boss, who is supposedly a
11 | decision-maker, may ultimately be, is unfounded on the record
12 | that's been submitted. And basically would require the Court
13 | to find that Mr. Reddy would violate protective order.

14 | But also it amounts to a restriction on Mr. Reddy's
15 | access based on fact that he has contact with the alleged
16 | competitive decision-maker, which is something that the
17 | Federal Circuit has rejected in Matsushita v. United States,
18 | 929 F.2d 1577 at page 1580, where the Federal Circuit said
19 | the Court found that the individual's position brought him
20 | into regular contact with executives who are involved in a
21 | day-to-day pricing and policy decisions in the context of
22 | what necessarily are competitive decision-making meetings.
23 | And then the Court says, These findings are largely
24 | irrelevant, since the standard is not relevant regular
25 | conduct with other corporate officials who make policy or

1 even competitive decisions, but advice and participation in
2 competitive decision-making.

3 So I think I've stated all the reasons. The Court
4 believes it's extremely unlikely there will be disclosure of
5 confidential information. I think the individuals are
6 important to managing the case. From what I've seen in the
7 declarations, the job duties of the individuals are not
8 competitive decision-making, and the Court is going to enter
9 a discovery confidentiality order that allows
10 Messrs. Thallemer and Reddy access to highly confidential
11 information.

12 And I guess you'll submit that order. I don't know
13 if we have -- do we have an order, Mr. Conlon at this point?
14 You may want to submit the order based on what I've said here
15 today.

16 I'm sorry that I read that into the record. I
17 would normally just put that in a letter to you or even a
18 short opinion, because it was long for you to sit here for
19 that. That takes care of that issue.

20 Is there anything we can do today? I want to thank
21 you for coming in. Is there anything I can do to move the
22 case forward, to resolve any other disputes, to -- whatever
23 there could be? Or is that it? Well, then I thank you very
24 much for coming in.

25 I -- as I said, when I deal with the patent cases,

1 which as you know, are a little more complex, I usually set
2 up regular meetings. And I only set up one more. If you
3 all -- if everything's going smoothly, call me two days in
4 advance or whenever you can, and we'll just talk by phone or
5 we'll skip the whole conference.

6 The issue of the expert that you asked me to, is I
7 want to take a quick look at that, and perhaps even have
8 contact with the district judge about how she prefers that
9 being done.

10 So what's the timing on you needing to know that in
11 the Markman context? Can you remind me?

12 MS. MELVIN: Your Honor, opening submissions are
13 due February 27th.

14 THE COURT: Right.

15 MS. MELVIN: Obviously, we would like to know a few
16 weeks in advance of that, if possible, so ...

17 THE COURT: And the way it is now is that the
18 defendants have a -- an expert? Is that what you're saying?
19 Or is -- I have it all wrong. You said it at the start of
20 the thing. The plaintiffs have an expert on this? Or you
21 haven't decided yet or what?

22 MS. MELVIN: So our position -- I don't know that
23 we have confirmed that we're going to use an expert.

24 THE COURT: Okay.

25 MS. MELVIN: But the position -- our position is

1 that if either party wants to use an expert in claim
2 construction, they should submit a declaration with the
3 opening paper and not just be able to only submit a
4 responsive declaration.

5 THE COURT: Yeah, we'll take a look at that. I've
6 actually recently had that come up in another patent case
7 with another district judge. And there were declarations
8 submitted. But I don't know if that's going to be the case
9 here.

10 Yes, sir.

11 MR. GRAHAM: Well, I was just going to point out
12 that one of the features of the rules, which is good, I like
13 these rules, but in 4.2(a) through (c), there is a specific
14 requirement with regard to disclosure of expert opinions.
15 And so that's what brought this on.

16 So hopefully we'll know better how to apply those
17 rules when we get to briefing, especially in regard to
18 rebuttal.

19 THE COURT: I mean, you're hitting on an issue that
20 I've confronted before in a sense, because, yeah, there
21 are -- you know, as I said, there's different views on what's
22 to be -- or what could be considered, and I mean -- oh, in
23 Markman, of course, there's been different views of what
24 you're dealing with there, whether it's, you know, pure
25 question of law or there's more to it, and why you need

1 experts, and -- but experts are referred to in the rule. I
2 hear you.

3 I'll try to come up with an answer for you. Okay?

4 And then maybe we'll send a letter or just call
5 you. I don't know.

6 MS. MELVIN: Your Honor, I just want to clarify one
7 thing. I think plaintiff's counsel is referring to -- we did
8 have some disagreement during the preparation of the joint
9 claim construction statement that plaintiffs felt that our
10 expert submission was insufficient. So we did supplement
11 that. So we have now a more detailed submission in the joint
12 claim construction statement.

13 So we did attempt to address those concerns. I
14 don't know if that's what he's referring to. But, you know,
15 our concern now is really with the briefing.

16 THE COURT: Okay. I mean, if there's a dispute
17 over the adequacy of the disclosure, which I'm not inviting,
18 that could be something that I could handle as well.

19 But we'll have a look. Excuse me for a second.

20 (Pause in proceedings)

21 THE COURT: Yeah, I mean, it's an interesting
22 aspect. It's something that in the rule -- and, you know,
23 I'm speaking although I mean I was a member of the committee
24 that adopted them, but there's been -- I'm not sure that
25 maybe there's something there that needs to be clarified,

1 but, you know, ultimately it comes down to, as you know, what
2 the district judges prefer. So ...

3 MR. GRAHAM: I would comment, Your Honor, just
4 closing, that one of the problematic aspects of claim -- of
5 Markman practice that I've encountered is this issue of
6 burden. And that, you know, in other areas of the law,
7 there's often an allocation of burden to one party or the
8 other. But one doesn't that find much with regard to claim
9 construction, which does make these kind of issues more
10 difficult to deal with in actual practice.

11 THE COURT: I appreciate your comment. It's a
12 subject of interest to me, but of course I'm not a patent
13 lawyer, per se, never was. But I hear what you're saying.
14 And I -- I think I do appreciate the issue. So we'll try to
15 get back to you right away, if we can.

16 Okay? Anything further? Thank you very much.

17 UNIDENTIFIED SPEAKERS: Thank you, Your Honor.

18 (Conclusion of proceedings at 10:57 A.M.)
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Certification

I, SARA L. KERN, Transcriptionist, do hereby certify that the 25 pages contained herein constitute a full, true, and accurate transcript from the official electronic recording of the proceedings had in the above-entitled matter; that research was performed on the spelling of proper names and utilizing the information provided, but that in many cases the spellings were educated guesses; that the transcript was prepared by me or under my direction and was done to the best of my skill and ability.

I further certify that I am in no way related to any of the parties hereto nor am I in any way interested in the outcome hereof.

s/ ***Sara L. Kern***

30th of January, 2017

Signature of Approved Transcriber

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